UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JUDITH KNIGHTS,	)	
	)	
Plaintiff,	)	
	)	**Civil Action No.**
v.	)	**19-11911-FDS**
	)	
C. R. BARD INCORPORATED and BARD PERIPHERAL VASCULAR INCORPORATED,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER ON
CROSS-MOTIONS FOR SUMMARY JUDGMENT

SAYLOR, C.J.

This is an action against a medical-device company arising from injuries allegedly sustained after the surgical implantation of one of its devices. Jurisdiction is based on diversity of citizenship.

According to the complaint, in 2013, plaintiff Judith Knights was diagnosed with deep vein thrombosis and a bilateral pulmonary embolism. In response, a surgeon implanted an inferior vena cava ("IVC") filter to prevent blood clots entering her heart and lungs. The complaint alleges that the device implanted was an "Eclipse" IVC filter designed and manufactured by defendants C.R. Bard Inc. and Bard Peripheral Vascular Inc. In 2014, that filter fractured, and a surgeon removed the filter and its separated piece. The complaint alleges that the fractured filter and subsequent surgery caused plaintiff various physical and emotional injuries.

The complaint asserts claims based on theories of strict liability; negligent design,

manufacture, and failure to warn; negligence *per se*; and breaches of implied and express warranties. It seeks both compensation and punitive damages.

Plaintiff has moved for partial summary judgment as to four affirmative defenses, of which defendants have agreed to withdraw two and part of a third. Defendants have moved for summary judgment on all ten claims asserted, of which plaintiff has agreed to withdraw five. For the following reasons, both motions, including the portions directed to the disputed claims, will be granted in part and denied in part.

I. Background

Except where otherwise noted, the following facts are undisputed.

A. The Parties

Judith Knights is a resident of Massachusetts. (Compl. ¶ 4, ECF No. 1).

C.R. Bard Inc. is a Delaware corporation with a principal place of business in New Jersey. (Master Compl. ¶ 11, ECF No. 11, Attach. 11). Bard Peripheral Vascular Inc. is a wholly-owned subsidiary of C.R. Bard Inc., with a principal place of business in Arizona. (*Id.* ¶ 12). Defendants designed, manufactured, and distributed the Eclipse IVC filter. (*Id.* ¶ 11-12).

B. The Eclipse Filter

IVC filters are prescription medical devices that have been available since the 1970s. They were first designed to be permanently placed for the rest of a patient's life. Because of the risks of complications associated with these early filters, retrievable filters were developed that could either be permanently implanted or later removed.

The FDA cleared the Eclipse filter as a Class II medical device through the "510(k)"

process as "substantially similar" to earlier filters. (MDL R., ECF No. 7, Attach. 6 at 2-7).[1]

The Eclipse filter was accompanied by Instructions for Use ("IFUs"), which contained information for physicians planning to treat a patient with the device. (ECF No. 78, Ex. 5).

C. Plaintiff's Implant

On April 10, 2013, Judith Knights was diagnosed with a deep vein thrombosis ("DVT") in her left leg and bilateral pulmonary emboli in her lungs. (Def. Mot. Summ. J., ECF No. 77, Ex. 7 at 6).

Dr. Edward M. Kwasnik evaluated Knights and advised her that "placement of a retrievable vena cava filter would be prudent at this time until the reason for her DVT is sorted out and decision is made requiring long term anticoagulation." (*Id.*). Based on that recommendation, she consented to have an IVC filter surgically implanted. (*Id.*). The next day, Dr. Kwasnik successfully emplaced a Bard Eclipse IVC filter. (*Id.* at 9-11; ECF No. 77, Ex. 8 at 3). She was discharged from the hospital on April 16, 2013. (Pl. Statement of Material Facts, ECF No. 78, Ex. 1 at 5-7). On August 29, 2013, Dr. Kwasnik met her to discuss a potential removal of the filter but assured her "removal of the filter [was] not necessary given the attendant complications . . . during the removal process." (ECF No. 77, Ex. 7 at 4).

About one year after the surgical implant, on April 26, 2014, a CT scan revealed that the IVC filter had fractured, and one metal prong had migrated to and perforated the right ventricle of the heart. (ECF No. 77, Ex. 8 at 6; Pl. Opp'n Summ. J., ECF No. 83, Ex. 43 at 12-13). Two days later, Dr. Piotr Sobiezcyk performed two surgical procedures to remove the filter and the

[1] New medical devices are usually subject to a premarket approval process by the Food & Drug Administration. *See* 21 U.S.C. § 360e. However, a manufacturer can obtain "clearance" to market a device through the alternative 510(k) process by showing that it is "substantially equivalent" to a device that is already available. 21 U.S.C. § 360(k). The FDA may only grant 510(k) clearance when the new device "is as safe and effective as a [predicate device] and . . . does not raise different questions of safety and efficacy than the predicate device." 21 U.S.C. § 360c(i)(1)(A)(ii).

separated filter arm. (ECF No. 83, Ex. 43 at 14-16).

D. Procedural Background

Defendants' IVC filters have been the subject of a multidistrict litigation proceeding initiated in 2015 and assigned to Judge David G. Campbell in the District of Arizona. *In re: Bard IVC Filters Prods. Liab. Litig.*, 2016 WL 3970338 (D. Ariz. July 25, 2016). Plaintiff filed this suit directly in that MDL on March 22, 2016. It was then transferred to this court on September 9, 2019.

The complaint alleges theories of strict liability; negligent design, manufacture, and failure to warn; negligence *per se*; and breaches of implied and express warranties.

On December 16, 2022, plaintiff moved for partial summary judgment as to four affirmative defenses. Defendants withdrew two of those defenses and part of a third, but otherwise opposed the motion.

On the same day, defendants moved for summary judgment on all ten of plaintiff's claims. Plaintiff agreed to withdraw five claims, including those alleging strict liability (Counts 1-3), negligent manufacture (Count 5), and negligence *per se* (Count 9), but otherwise opposed the motion. (Pl. Opp'n Summ. J. at 1 n.1).[2]

II. Standard of Review

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Mesnick v. General Elec. Co.*, 950 F.2d 816, 822 (1st Cir. 1991) (quoting *Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990)). Summary judgment shall be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A genuine

[2] The *pro forma* complaint includes counts not alleged against defendants. (Compl. ¶ 12). The Court will use the numbered counts as employed in the complaint for clarity.

issue is "one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant, would permit a rational factfinder to resolve the issue in favor of either party." *Medina-Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990) (citation omitted). In evaluating a summary judgment motion, a court indulges all reasonable inferences in favor of the nonmoving party. *See O'Connor v. Steeves*, 994 F.2d 905, 907 (1st Cir. 1993). When "a properly supported motion for summary judgment is made, the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (quotations omitted). The nonmoving party may not "rest upon mere allegation or denials of his pleading," but must "present affirmative evidence." *Id.* at 256-57.

III. Defendants' Motion for Summary Judgment

Plaintiff has agreed to withdraw Counts 1-3, Count 5, and Count 9. As a result, the Court will grant summary judgment as to those counts and only address the disputed issues.

A. Local Rule 56.1

Plaintiff contends that defendants' motion should be denied for failing to comply with the requirements of Local Rule 56.1 that motions for summary judgment "include a concise statement of the material facts of record as to which the moving party contends there is no genuine issue to be tried, with page references to affidavits, depositions and other documentation." L.R. 56.1.

Both parties submitted "Facts" sections, but neither claimed those facts were undisputed. There is no clear accounting of which facts are disputed, and arguably both parties have violated the Local Rule. *See United States v. Pfizer, Inc.*, 188 F. Supp. 3d 122, 128 (D. Mass. 2016). Plaintiff chose not to respond directly to defendants' factual assertions based on the contention that defendants had not complied with L.R. 56.1. (Pl. Opp'n Summ. J. at 2).

Nonetheless, "district courts enjoy broad latitude in administering and enforcing local rules," and a court may treat incorporated statements of fact as sufficient to satisfy L.R. 56.1. *Katsiaficas v. U.S. Central Intel. Agency*, 2017 WL 2172437, at *1 (D. Mass. May 17, 2017) (quotation omitted). The Court will endeavor to determine which material facts are, in truth, disputed, based on the submissions of the parties.

B. Negligence Claims

Defendants contend that summary judgment should be granted as to the negligence claims because (1) plaintiff has failed to produce evidence that there was a feasible and safer alternative design for a retrievable IVC filter, and (2) plaintiff has not met her burden to show that defendants' warnings about the risks of the Eclipse filter were inadequate or, even if they were, that different warnings would have changed Dr. Kwasnik's treatment decisions.

1. Design Defect

To prove a design-defect claim, a plaintiff must "prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm." *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 428 (2013) (quoting RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. f (1998)). A plaintiff must show that "the product in question could have been more safely designed, not that a different product was somehow safer." *Tersigni v. Wyeth*, 817 F.3d 364, 368 (1st Cir. 2016).

Defendants contend that plaintiff cannot prevail on her design-defect claim because she has not pointed to a safer alternative design for retrievable IVC filters. Plaintiff counters that permanent filters should be considered alternative designs for retrievable filters, such as the Eclipse filter, because a retrievable filter is also "designed to be used . . . on a permanent filter basis." (ECF No. 83, Ex. 44 at 30:15-16, Deposition of Dr. Edward M. Kwasnik). In addition, plaintiff cites evidence that (she asserts) shows that defendants' "G2" line of filters, which

includes the Eclipse filter, had higher rates of migration and fracture than their earlier "Recovery" model. (Pl. Opp'n Summ. J. at 19 (citing Ex. 26)).

On the present record, there appears to be a factual dispute over whether permanent and retrievable filters should be considered as alternative designs to one another. Defendants cite multiple cases, including one arising from this MDL, where courts have concluded that they are not sufficiently similar to be alternatives. *See, e.g.*, *Couturier v. Bard Peripheral Vascular, Inc.*, 548 F. Supp. 3d 596, 609 (E.D. La. 2021) (applying Louisiana law); *Oden v. Boston Sci. Corp.*, 330 F. Supp. 3d 877, 889 (E.D.N.Y. 2018) (applying New York law to find that "a permanent filter[] is not comparable to a retrievable filter, since the design and purpose of these two products is different"); *Tears v. Boston Sci. Corp.*, 344 F. Supp. 3d 500, 510 (S.D.N.Y. 2018) (same). There are, however, at least some cases deciding the other way. *See, e.g.*, *In re Bard IVC Filters Prods. Liab. Litig.*, *Hyde v. C.R. Bard Inc.*, 2018 WL 4742976, at *3 (D. Ariz. Oct. 2, 2018) (denying judgment as a matter of law in an MDL bellwether case, applying Wisconsin law, finding "[w]hether the retrievability of the . . . Eclipse made [it] sufficiently unlike the [permanent filter] to disqualify the [permanent filter] as a reasonable alternative design is a question for the jury to decide."); *Banks v. C.R. Bard, Inc.*, 2022 WL 17490977, at *3 (M.D. La. Dec. 7, 2022) (finding a "genuine factual dispute" as to whether a permanent filter was a safer alternative to the retrievable G2 filter); *Johnson v. C.R. Bard Inc.*, 2021 WL 1784661, at *9 (W.D. Wis. May 5, 2021) (same, applying Wisconsin law); *Munson v. C.R. Bard, Inc.*, 561 F. Supp. 3d 655, 678 (N.D. Miss. 2021) (same, applying Mississippi law).[3]

It may well be the case, as multiple courts have concluded, that a permanent filter is not

[3] It is unclear whether plaintiff's Exhibit 26, which she contends shows that the earlier "Recovery" model was a safer design to the G2, actually supports that assertion. (ECF No. 83, Ex. 26).

an alternative to a retrievable filter. However, under the circumstances, and at least on the present record, there appears to be a disputed issue of material fact as to whether that is true. Summary judgment will therefore be denied as to that claim.

2. Failure to Warn

The complaint alleges that defendants negligently failed to warn plaintiff of the risks associated with the implantation of the Eclipse filter. She contends that any warning given was inadequate and that an adequate warning "might have altered Dr. Kwasnik's decision to implant [plaintiff] with the Eclipse." (ECF No. 83 at 21).

"A manufacturer of a product has a duty to warn foreseeable users of dangers in the use of that product of which he knows or should have known." *Mitchell v. Sky Climber, Inc.*, 396 Mass. 629, 631 (1986). A manufacturer may be liable "even if the product does exactly what it is supposed to do, if it does not warn of the potential dangers inherent in the way a product is designed." *Laaperi v. Sears, Roebuck & Co.*, 787 F.2d 726, 729 (1st Cir. 1986). "It is not necessary that the product be negligently designed or manufactured." *Id.*

Under the "learned intermediary" doctrine, a medical-device manufacturer's obligation to warn of dangers associated with its product runs to the physician, not the patient. *Cottam v. CVS Pharm.*, 436 Mass. 316, 321 (2002); *Langlois v. American Med. Sys.*, 462 F. Supp. 3d 1, 4 (D. Mass. 2020). A plaintiff "carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 81 (1st Cir. 1992). Factors relevant to determining the adequacy of a warning include:

> whether the warning adequately indicates the scope of the danger; whether the warning reasonably communicates the extent or seriousness of the harm that could result from misuse of the product; whether the physical aspects of the warning adequately alert a reasonably prudent person to the danger; and whether the means to convey the warning are adequate in the given circumstances.

Albright v. Boston Sci. Corp., 90 Mass. App. Ct. 213, 220 n.17 (2016) (citing *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004)).

Here, plaintiff contends the warning given to her physician in the Eclipse's IFUs was inadequate because it failed to provide enough information about the safety and efficacy of its retrievable filters—specifically, their fracture rate. She offers the report of Dr. Derek Muehrecke, who has concluded that the IFUs were inadequate to warn physicians about the scope of risks associated with the Eclipse filter. (ECF No. 83, Ex. 42 at 16-18). She also offers the report of Dr. Lincoln Patel, who submits that defendants' failure to communicate the safety information allegedly available at the time of plaintiff's surgery "prevented him from making an informed decision" as to whether to use the Eclipse filter. (ECF No. 83, Ex. 40 at 17). Those opinions establish a triable issue of fact concerning the adequacy of defendants' warnings.

If plaintiff has satisfied the initial burden of providing evidence that the warning was inadequate, "a rebuttable presumption arises that the physician would have heeded an adequate warning . . . defendant[s] must then come forward with sufficient evidence to rebut that presumption . . . [O]nce the presumption is rebutted, plaintiff must produce sufficient evidence to create a triable issue on the question of causation." *Garside*, 976 F.2d at 81 (citations omitted).

Defendants assert that "even if a jury question about adequacy exists, [p]laintiff still cannot prove the causation element of her claim"—in other words, that she has not submitted sufficient evidence that an adequate warning would have changed Dr. Kwasnik's treatment decisions. (ECF No. 77 at 13). Defendants contend that Dr. Kwasnik testified in his deposition that he was aware of the risks of IVC filters, and that he would still have used an Eclipse filter even after being made newly aware of treatment risks. (ECF No. 77, Ex. 11 at 103). Plaintiff disputes that reading and contends that he might have used a different IVC filter or ensured that

other IVC filters would be available. (Pl. Opp'n Summ. J. at 21).

Defendants also note Dr. Kwasnik testified that he "would have to study" any material comparing the risks of Eclipse filters to other IVC filters before deciding it would have changed his treatment decision. (ECF No. 7, Ex. 11 at 86:4-20). They contend his testimony is not sufficient evidence that including the additional information would have changed his decision.

Drawing all reasonable inferences in favor of plaintiff, Dr. Kwasnik's testimony is not sufficient, for purposes of summary judgment, to rebut the presumption that he would have heeded a different warning had defendants supplied one. Accordingly, defendants' motion for summary judgment as to Count 7 will be denied.

C. Warranty Claims

1. Breach of Express Warranty

Plaintiff alleges that defendants expressly represented that the Eclipse filter was safe and effective. Although she does not contend that defendants had direct contact with her, she asserts that because of the learned intermediary doctrine, the warranties extend through Dr. Kwasnik. (Pl. Opp'n Summ. J. at 23).

Under Massachusetts law, an express warranty can be created in three ways:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the sample or model.

Mass. Gen. Laws ch. 106 § 14. "Because the standard of performance is set by defendant's express promises to the plaintiff, 'the plaintiff must demonstrate that the defendant promised a

specific result' and that defendant failed to deliver on his promise and, therefore, breached the express warranty." *Jackson v. Johnson & Johnson & Janssen Pharms., Inc.*, 330 F. Supp. 3d 616, 627 (D. Mass. 2018) (quoting *Anthony's Pier Four, Inc. v. Crandall Dry Dock Eng'rs, Inc.*, 396 Mass. 818, 823 (1986)). "Furthermore, in an express warranty claim, plaintiff must show reliance on such warranty." *Sprague v. Upjohn Co.*, 1995 WL 376934, at *3 (D. Mass. May 10, 1994) (citing *Roth v. Ray-Stel's Hair Stylists, Inc.*, 18 Mass. App. Ct. 975, 976 (1984)).

Courts evaluating express-warranty claims must look to the specific affirmations or promises made by a defendant. *See, e.g.*, *Niedner v. Ortho-McNeil Pharm., Inc.*, 90 Mass. App. Ct. 306, 313 (2016). If a plaintiff has not identified a specific affirmation or promise, then a factfinder cannot evaluate whether the affirmation or promise relates to the goods, whether the affirmation or promise is part of the basis of the bargain, or whether the goods conform to the affirmation or promise. *See Taupier v. Davol, Inc.*, 490 F. Supp. 3d 430, 438 (D. Mass. 2020).

Here, plaintiff's only alleged affirmation or promise by defendants is from the Eclipse IFUs, which state that the filter "is designed to act as a permanent filter." (ECF No. 77, Ex. 3 at 4). She asserts that statement amounts to an express warranty. (Pl. Opp'n Summ. J. at 23). To bolster her assertion, she offers Dr. Kwasnik's testimony that he read the Eclipse IFUs. (ECF No. 83, Ex. 44 at 57:13-20). Even assuming the IFUs are an affirmation or promise that the Eclipse can be "permanent," plaintiff has produced no evidence establishing that Dr. Kwasnik specifically relied on that phrase or that it induced him to use the Eclipse filter. Accordingly, defendants' motion for summary judgment as to Count 10 will be granted.

2. Breach of Implied Warranty

Defendants contend that plaintiff cannot sustain her claim for a breach of implied warranty because IVC filters, including the Eclipse filter, are "unavoidably unsafe" within the meaning of comment k to Section 402A of the Restatement (Second) of Torts. Even if they are

not, defendants assert that plaintiff's implied warranty claim should fail for the same reasons as her negligence claims.

In Massachusetts products-liability cases, breach of implied warranty claims are functionally identical to strict-liability claims in other jurisdictions. *See Commonwealth v. Johnson Insulation*, 425 Mass. 650, 653-54 (1997). "Liability under this implied warranty is congruent in nearly all respects with the principles expressed in the RESTATEMENT (SECOND) OF TORTS § 402A (1968)." *Id.* (quotation omitted).

Comment k to § 402 acknowledges that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and are not defective nor unreasonably dangerous when properly prepared and accompanied by appropriate warnings. RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (1968). "In Massachusetts, comment k has been applied to shield manufacturers of prescription drugs from claims of breach of the implied warranty of merchantability," but "neither the [Supreme Judicial Court], the Massachusetts Appeals Court, nor the First Circuit has addressed the question of whether Massachusetts applies comment k to bar breach of warranty claims for defectively designed implanted medical devices." *Taupier*, 490 F. Supp. 3d at 441.

Defendants urge the court to extend the application of comment k to the medical-device context and to conclude, as a matter of undisputed fact, that the implied warranty claim necessarily fails. The Court declines to do so, both because Massachusetts law is not settled in this area and, even assuming comment k applies, the factual issue of whether a medical device is "quite incapable of being made safe" cannot be resolved at this stage.[4]

Accordingly, defendants' motion for summary judgment as to Count 10 will be denied.

[4] Defendants' further contentions that the implied warranty claim should nonetheless fail for the same reasons as her negligence claims do not warrant summary judgment for the reasons stated above.

D. Punitive Damages

Defendants contend that the claim for punitive damages should be dismissed because Massachusetts law does not permit an award of punitive damages under the circumstances presented here.

Under Massachusetts law, punitive damages are not permitted "unless expressly authorized by statute." *Flesner v. Technical Commc'ns Corp.*, 410 Mass. 805, 813 (1991). Plaintiff concedes that no Massachusetts statute would authorize punitive damages here. (Pl. Opp'n Summ. J. at 23). Accordingly, defendants' motion for summary judgment as to the claim for punitive damages claim will be granted.

IV. Plaintiff's Motion for Summary Judgment on Affirmative Defenses

Plaintiff has also moved for summary judgment on certain affirmative defenses. Specifically, she contends that summary judgment is appropriate for affirmative defenses involving (1) assertions that plaintiff "caused, contributed to, or assumed the risk" of her alleged injuries; (2) statutes of limitations and/or repose periods; (3) federal preemption; and (4) waiver, estoppel, and/or laches.

Defendants have agreed to withdraw their affirmative defenses as to the expiration of statutes of limitations and/or repose periods (Defense 3) and waiver, estoppel, and/or laches (Defenses 24 and 28). (Def. Opp'n Summ. J., ECF No. 81, at 1). They have also agreed to withdraw the remaining affirmative defenses related to causation "to the limited extent they pertain to the conduct or fault" of plaintiff. (*Id.*).

There are three points of contention between the parties. First, defendants seek to ensure that plaintiff will continue to bear the burden of proving causation, despite their assertion of causation as an affirmative defense. Second, they reserve their defense of informed consent and assumption of the risk. And third, they contend the issue of federal preemption (Defense 7) is

moot because the issue was determined by the MDL court. (*Id.*). The Court will grant summary judgment as to the withdrawn defenses and only specifically address the disputed issues.

A. Causation

"Cause in fact and proximate causation are required to establish a claim for breach of implied warranty of merchantability and negligence." *Goodrich v. Cequent Performance Prods., Inc.*, 285 F. Supp. 3d 432, 436 (D. Mass. 2018) (citing *Staelens v. Dobert*, 318 F.3d 77, 79 (1st Cir. 2003); *Lubanski v. Coleco Indus., Inc.*, 929 F.2d 42, 48 (1st Cir. 1991)). Because causation is a *prima facie* element of plaintiff's claims, a defendants' direct challenges to actual or proximate causation are not affirmative defenses. *See* FED. R. CIV. P. 8(c). Instead, they are properly considered specific denials, even if they are initially mislabeled as "defenses." *See* 5 WRIGHT & MILLER, FED. PRAC. & PROC. CIV. § 1269 (4th ed. 2023). In such cases, courts should ignore the mistaken identifier and treat them as denials. *Id.*

Here, defendants' contentions regarding proximate cause (Defenses 2 and 20) and superseding or intervening causes (Defenses 8 and 18) should be properly considered as specific denials, rather than affirmative defenses, because they are direct challenges to plaintiff's primary case. As specific denials, they present material issues of fact that cannot be resolved at summary judgment. Accordingly, plaintiff's motion, to the extent that it implicates those assertions, will be denied.

B. Assumption of Risk

Under Massachusetts law, the affirmative defense of assumption of risk has been abolished in negligence actions. Mass. Gen. L. § 85. Instead, it has been subsumed into a modified comparative-negligence regime. *Id.* It is well-established that "[t]he question of comparative negligence, like that of breach of duty, is primarily for the factfinder." *Marquez v. Home Depot USA, Inc.*, 154 F. Supp. 2d 152, 156 (D. Mass. 2001).

In warranty actions, however, "the only duty imposed on the user is to act reasonably with respect to a product which [she] knows to be defective and dangerous." *Correia v. Firestone Tire & Rubber Co.*, 388 Mass. 342, 355 (1983). Proof of breach of that duty requires evidence that a plaintiff "relinquished the law's protection" by continuing to use a product she "kn[ew] to be defective and dangerous." *Id.*

Here, defendants purport to oppose plaintiff's motion on the ground that they should be allowed to present evidence at trial that plaintiff consented to the procedure. That contention, however, is not an assumption-of-risk defense, or even a comparative negligence defense. Indeed, the evidence they cite, including plaintiff's signed consent form and the expert testimony of Dr. Christopher Morris, do not support the assertion that plaintiff knew that the product was defective and dangerous, (ECF No. 81, Ex. 8; Ex. 1 at 3), and there is no evidence that plaintiff acted negligently in agreeing to the implant procedure.

Accordingly, plaintiff's motion for summary judgment as to the affirmative defense of assumption of risk will be granted.

C. Preemption

Plaintiff contends that her state-law claims are not barred by federal preemption. (Pl. Mot. Summ. J. at 5-6). Defendants assert that the issue is moot because the MDL court denied their motion for summary judgment based on preemption. (Def. Opp'n Summ. J. at 6). *See also In re Bard IVC Filters Prods. Liab. Litig.*, 2017 WL 5625547, at *5 (D. Ariz. Nov. 22, 2017), *aff'd*, 969 F.3d 1067 (9th Cir. 2020).

In multidistrict litigation, a successor court should respect the decisions of an MDL court under the law-of-the case doctrine. That doctrine "posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Arizona v. California*, 460 U.S. 605, 618 (1983). Although the successor court may

"vacate or modify" prior decisions of the MDL court, disturbing those rulings "in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings." MANUAL FOR COMPLEX LITIGATION § 20.133 (4th ed. 2004); *see also In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1176 (D.C. Cir. 1987), *aff'd sub nom. Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122 (1989).

Here, the question is not moot because it could be revisited by this court. However, defendants offer no reason to reexamine the rulings of the MDL court as to their preemption defense. Accordingly, plaintiff's motion for summary judgment as to Defense 7 will be granted.

V. Conclusion

For the foregoing reasons, defendants' motion for summary judgment on Count 1, Count 2, Count 3, Count 5, Count 9, and Count 10, and as to the claim for punitive damages, is GRANTED, and otherwise DENIED. Plaintiff's motion for partial summary judgment on Defense 3, Defense 4, Defense 7, Defense 24, and Defense 28 is GRANTED; GRANTED in part as to Defense 21 and Defense 26; and otherwise DENIED.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court

Dated: September 20, 2023